

## **REMARKS**

### ***Status of the Claims***

Claims 57, 70-71 and 88 are currently pending in this application upon entry of this paper. Relative to the previously pending claim set, claim 57 has been amended to more clearly recite the claimed invention. No new matter has been added by the amendments.

### ***The Claims are Not Obvious***

The Office Action rejects claims 57, 70, 71 and 88 as allegedly obvious in view of Saulnier *et al.* (EP Patent No. 320988) ("Saulnier"). Applicants respectfully disagree with the Examiner and assert and incorporate by reference the previous arguments of record. Nonetheless, to expedite prosecution, Applicants have amended claim 57. Applicants assert that the claim amendments render moot the obviousness rejection. Specifically, Saulnier only discloses etoposide and teniposide and does not specifically teach or suggest cis- or trans-n-9 monounsaturated fatty acids in combination with the remaining therapeutics listed in the claims. Since Saulnier does not teach each and every limitation of the claimed invention, the cited reference must necessarily fail to render obvious the currently claimed invention.

The Office Action alleges that, even though Saulnier fails to disclose 9-monounsaturated fatty acid derivatives, the claimed invention would still be obvious because "an ordinary artisan would have a reasonable expectation that any of the species of the genus [disclosed in Saulnier] would have similar properties." *Office Action of 16 December 2009*, page 4. First, Saulnier is focused on etoposide or teniposide derivatives, not on preparing conjugates of anticancer drugs to a fatty acid. The "alkenyl" language used in Saulnier is simply language used to expand the derivatives of etoposide or teniposide and does not teach covalently bonding compounds to a monounsaturated fatty acid. Applicants assert that one of skill would not view Saulnier as teaching or suggesting covalently bonding fatty acids to anti-cancer drugs.

Second, Applicants note that the current claims are directed to specific fatty acids and not every possible alkenyl as defined by Saulnier. Indeed, Saulnier defines alkenyl as a straight or branched chain with at least one double bond. Thus, the genus as defined by Saulnier can

include any carbon chain with 2 to 20 carbon atoms and at least one double bond at any location on the carbon chain or carbon branch. This definition therefore encompasses monounsaturated and polyunsaturated fatty acids of any size and with any number of double bonds at any location. It is well-established that the physical properties of fatty acids will vary with their degree of saturation or unsaturation. *See Voet, D. and Voet, J., Biochemistry*, 2<sup>nd</sup> Ed. John Wiley & Sons, Inc. 1995, Ch. 11, an excerpt of which is appended hereto. Accordingly, the genus as defined by Saulnier is very large, and contrary to the Office's assertions, not all members of the genus would be expected to have similar properties. For example, one of skill in the art will readily appreciate that a fatty acid with 3, 4, 5 or more double bonds in the carbon chain will have very different properties than a monounsaturated fatty acid chain.

Moreover, there is nothing in the cited art or of record that would explain why one of skill in the art would select the specifically claimed fatty acids. Although Saulnier may allegedly disclose a genus of alkenyls that encompass the claimed fatty acids, there is nothing of record that would rationally explain why one of skill would choose the specifically claimed fatty acids. Indeed, Example 11 of Saulnier, which the Office cites to on page 4 of the Office Action, shows etoposide with a polyunsaturated fatty acid (2 double bonds) appended thereto. The claims, however, specifically recite a monounsaturated fatty acid. Thus, even though Saulnier discloses, in very general terms, the definition of alkenyl, there is nothing in Saulnier to guide one of skill in the art to choose the specifically claimed fatty acids. Moreover, the Office has not provided any rational or basis that one of skill in the art would have in choosing the specific fatty acids claimed.

Accordingly, Applicants assert that the presently claimed invention is not obvious in view of Saulnier. First, Saulnier does teach each and every limitation of the claimed invention. Second, Applicants respectfully disagree that one of skill in the art would expect all members of the genus specified in Saulnier to behave similarly. Applicants have provided evidence to contrary herewith. In addition, because one of skill would not expect each member the genus disclosed in Saulnier to behave similarly, the Office must provide some reasoning or rationale as to why one of skill would select the fatty acids specifically claimed. The Office has failed to do

so. Accordingly, Applicants assert that the claimed invention would not be obvious in view of Saulnier. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection.

### **CONCLUSIONS**

Applicants have amended claim 57 to expedite prosecution and assert that Saulnier does not render obvious the currently pending claims. Applicants respectfully request reconsideration and withdrawal of all outstanding rejections.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any necessary fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17, which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a Constructive Petition for Extension of Time in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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